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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,033	04/24/2006	Wolfgang Stahle	24945-0031	9140

49442 7590 06/26/2007

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EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
06/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,033	STAHLE ET AL.	
	Examiner	Art Unit	
	Noble Jarrell	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 17-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14,17-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-14 and 17-36 are pending in the current application.

2. This is a National Stage of PCT/EP04/11550, filed October 14, 2004, which claims priority to Germany 103 49 587, filed October 24, 2003.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claims 1-9, 11, 25-26, drawn to compounds of formula 1 wherein variable L is oxygen, E, G, U, and Q are C, and M is N (forming a pyridine ring), and the L group is connected to the pyridine ring at the 3 or 4 position.

Group II, claims 1-9, 11, 25-26, drawn to compounds of formula 1 wherein variable L is oxygen, E, G, and Q are C, and U and M is N (forming a pyrimidine ring), and the L group is connected to the pyrimidine ring at the 4 position.

Group III, claims 1-9, 11, 25-26, drawn to compounds of formula 1 not covered by groups I or II.

Groups IV-VI, claim 10, drawn to a method of preparing compounds of groups I-III, respectively.

Groups VII-IX, claims 12-14, 17-19, 24 (in part), 30-33, and 36, drawn to a method of using compounds in the treatment of cancer, respectively.

Groups X-XII, claims 12-14, 30-32, 34, 35, drawn to a method of using compounds of groups I-III in the treatment of non-cancerous diseases, respectively.

Groups XIII-XV, claims 12, 20-22, drawn to a method of using compounds of groups I-III in the treatment of ocular diseases, respectively.

Groups XVI-XVIII, claims 12, 20, 22 (in part), 23, drawn to a method of using compounds of groups I-III in the treatment of inflammatory diseases, respectively.

Groups XIX-XXI, claims 12, 20, 24 (in part), drawn to a method of using compounds of groups I-III in the treatment of bone diseases that are non-cancerous, respectively.

Groups XXII-XXIV, claims 12, 27-28, drawn to a method of using compounds of groups I-III in combination with another compound, respectively.

Groups XXV-XXVII, claims 12, 29, drawn to a method of using compounds of groups I-III in combination with a growth-factor receptor inhibitor, respectively.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a

large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables E, G, M, Q, and U result in many permutations giving both heteroaromatic and carbocyclic aromatic rings, different bonds between atoms, resulting in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Formula I is also broad because variable L consists of 10 different connecting groups and the fact that L can connect at any point on the phenyl ring. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:

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=> d que sta
L3                STR
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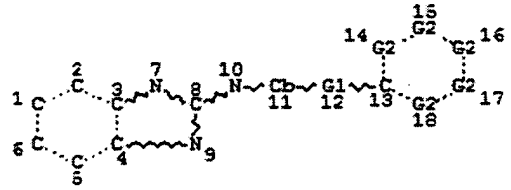

```
REP G1=(1-2) A
VAR G2=C/N
NODE ATTRIBUTES:
DEFAULT MLEVEL IS ATOM
GGCAT   IS MCY  UNS  AT  11
DEFAULT ECLEVEL IS LIMITED
ECOUNT  IS E6 C  AT  11

GRAPH ATTRIBUTES:
RING(S) ARE ISOLATED OR EMBEDDED
NUMBER OF NODES IS  18

STEREO ATTRIBUTES: NONE
L4              2 SEA FILE=REGISTRY SSS SAM L3

 37.1% PROCESSED    2000 ITERATIONS                          2 ANSWERS
INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)
SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS:  ONLINE  **COMPLETE**
                        BATCH   **COMPLETE**
PROJECTED ITERATIONS:       103437 TO   112243
PROJECTED ANSWERS:               2 TO      246
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Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

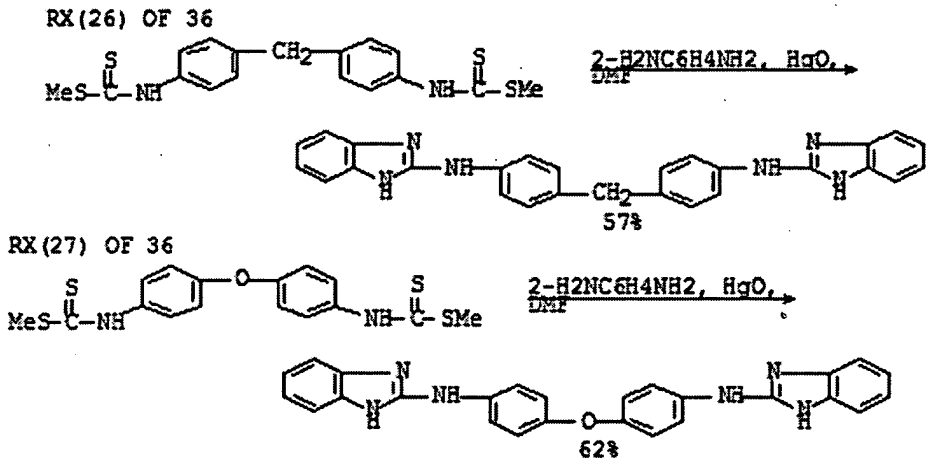
4. Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the ring formed by variables E, G, M, Q, and U is different. In invention I, the variables form a pyridine ring that is connected to the L variable (oxygen) at the 3 or 4 position of pyridine. In invention II, the variables form a pyrimidine ring that is connected to the oxygen at its 4 position. Invention III covers any compounds not covered by inventions I or II, and therefore, could be a triazine ring that is connected to the phenyl ring through variable L. Each invention is also classified differently because of the ring that can form from variables E, G, M, Q, and U. Because each of these inventions has a different core structure as a result of the ring formed by variables E, G, M, Q, and U, and each invention requires a different structure search, there is a search burden to examine all of the inventions concurrently.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

6. Inventions I-III and VII-XXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case compounds of formula I can also be used as gonadotropin-releasing hormone receptor antagonists.

7. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

8. Inventions IV-VI and I-III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case compounds of formula I can be made a different way, which is shown below.



The final products of these reactions are valid compounds under formula I.

9. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

10. Inventions VII-IX, X-XII, XIII-XV, XVI-XVIII, XIX-XXI, and XXII-XXIV, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions The following table shows the subject matter of each group of inventions.

INVENTIONS	SUBJECT MATTER
VII-IX	Cancerous diseases
X-XII	Method of treating an non-cancerous diseases not included in groups XIII-XXIV
XIII-XV	Method of treating an ocular disease
XVI-XVIII	Method of treating inflammatory disease
XIX-XXI	Method of treating a non-cancerous bone disease
XXII-XXIV	Combinations of compounds of formula I with another compound
XXV-XXVII	Combinations of compounds of formula I with a growth-factor receptor inhibitor

Each group of inventions covers a different type of disease and a different population of patients. The population that is being treated for cancer is not necessarily the same population that is being treated for an ocular disease. This argument can be applied to each of the different groups. Groups VII-IX and

X-XII are different because VII-IX apply to cancerous diseases and X-XII apply to non-cancerous diseases. Groups X-XII are different from XII-XXI because "non-cancerous diseases" is much broader in scope than the diseases cited in groups XIII-XXI. Groups XXII-XXIV and XXV-XXVII are different form one another because growth-factor receptor inhibitors are not included in the group of compounds in claims 27 and 28.

11. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

12. Applicant is advised that the reply to this requirement to be complete must include the invention to be examined. Applicant is advised that in addition to the election requirement a reply must include an identification all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. If claims are added after the election, applicant must indicate which are readable upon the elected invention. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an

identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

If applicants elect any one of groups VII-XXI, they must also elect a specific disease.

If applicants elect any one of groups XXII-XXIV, they must also elect a specific type of inhibitor.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is 571 (272) 9077. The examiner can normally be reached on Mon-Fri 7:30 A.M.-6:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NJ

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER